# Patients' Preference for *Veramyst* Nasal Spray

This information is provided in response to your request for information about Veramyst® (fluticasone furoate) Nasal Spray.

## SUMMARY


- In clinical trials, the majority of adults and adolescents aged 12 years and older completing a product characteristic questionnaire found that *Veramyst* Nasal Spray was easy to carry and operate, comfortable to administer, and that the mist generated by the device was gentle.
- Approximately one-third of patients experienced no medication leakage from the nose or down the throat and approximately half reported no aftertaste following administration of *Veramyst*.
- The results of a multicenter, double-blind, single-dose, crossover study suggest that *Veramyst* has sensory attributes that are preferable when compared with those of fluticasone propionate nasal spray (FPNS). Significantly more patients preferred *Veramyst* overall and on individual sensory attributes of odor, taste, aftertaste, dripping down the throat, and nose run-off.
- Important safety information is found in the attached Prescribing Information.


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## PATIENT PREFERENCE FOR *VERAMYST*

Patients who participated in clinical studies for *Veramyst* completed a product characteristic questionnaire consisting of 6 subjective questions pertaining to their experience with the nasal spray device. The questions encompassed portability and acceptability of the device and perceptions regarding aftertaste, spray "run-off" following administration, and spray sensation. This questionnaire has not been validated but was used to gather data on the product.

### Patient Preference for *Veramyst* in Seasonal Allergic Rhinitis (SAR)

Patients' experience with *Veramyst* Nasal Spray 110 mcg once daily (QD) in the morning was evaluated in 3, 2-week, double-blind, randomized, parallel-group, placebo controlled trials.[1,2,3] Studies 1 (N=299), 2 (N=285), and 3 (N=302) consisted of patients ≥12 years of age who had a diagnosis of SAR due to ragweed, grass pollen and mountain cedar, respectively. Results from the product characteristic questionnaire demonstrated that 91%-95% of patients with SAR found the nasal spray device to be somewhat easy to extremely easy to carry (Table 1). Eighty-two percent (82%) to 91% found the device to be somewhat easy to extremely easy to operate. The nasal spray nose tip was considered comfortable or extremely comfortable during administration of the spray by 93%-97% of patients. The mist generated by the device was rated as moderately to extremely gentle by 78%-93% of study participants. Approximately, one-third of patients reported no medication leakage out of the nose or down the throat. Most patients reported no aftertaste (52%-55%) or only a weak aftertaste (35%-36%) following administration of *Veramyst*.

### Patient Preference for *Veramyst* in Perennial Allergic Rhinitis (PAR)

Patients' experience with *Veramyst* Nasal Spray was evaluated in a 4-week, double-blind, randomized, parallel-group, placebo-controlled study (N=302).[4] Patients ≥ 12 years of age with a diagnosis of PAR symptomatic to animal dander, house dust mites, cockroaches, and/or mold were randomized to treatment with *Veramyst* 110 mcg or vehicle placebo QD in the morning (4).

Product questionnaire results demonstrated that 94% of patients with PAR found the nasal spray device somewhat easy to extremely easy to carry (Table 1). Seventy-eight percent (78%) found the device to be somewhat easy to extremely easy to operate. The nasal spray nose tip was considered comfortable or

extremely comfortable during administration of the spray by 95% of patients. The mist generated by the device was rated as moderately to extremely gentle by 90% of study participants. Thirty-eight percent (38%) of patients reported no medication leakage from the nose or down the throat. Approximately half of the patients (54%) reported no aftertaste or only a weak aftertaste (38%) following administration of *Veramyst*.

**Table 1. Summary of Product Characteristic Questionnaire and Patient Preference for *Veramyst***

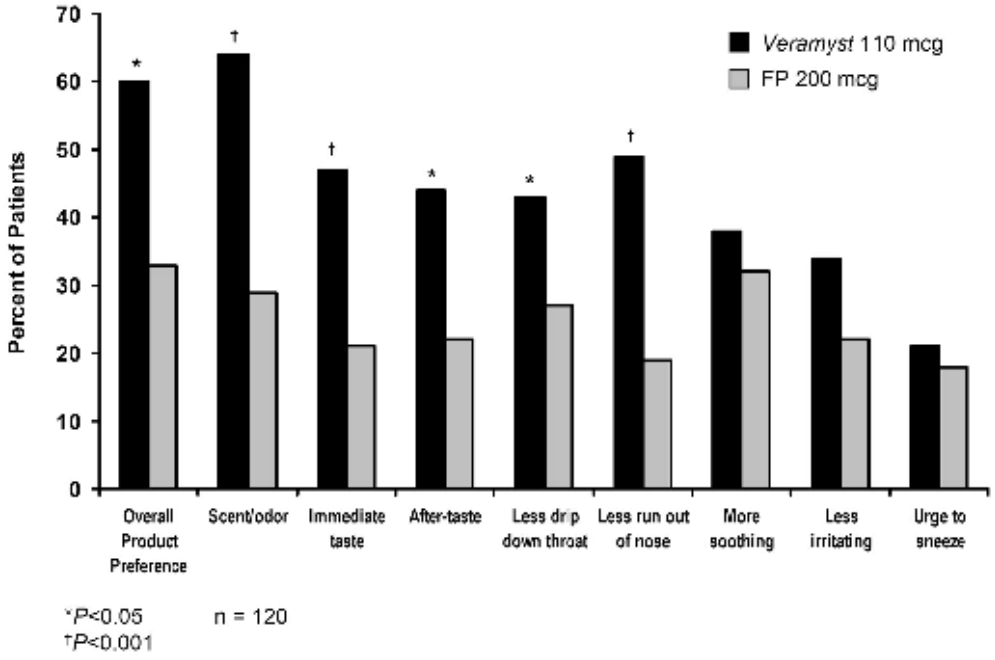
| **Characteristic** | **SAR** | | | **PAR** |
|---|---|---|---|---|
| | **Study 1 (N=299)** | **Study 2 (N=285)** | **Study 3 (N=302)** | **Study 4 (N=302)** |
| | **n (%)** | **n (%)** | **n (%)** | **n (%)** |
| **Ease in carrying the nasal spray** | | | | |
| Extremely easy | 189 (63) | 139 (49) | 197 (65) | 186 (62) |
| Somewhat easy | 97 (32) | 121 (42) | 90 (30) | 97 (32) |
| Somewhat difficult | 6 (2) | 23 (8) | 13 (4) | 13 (4) |
| Extremely difficult | 3 (1) | 0 | 1 (<1) | 3 (<1) |
| Missing data | 1 (<1) | --- | | 2 (<1) |
| **Ease in operating the nasal spray** | | | | |
| Extremely easy | 184 (62) | 111 (39) | 168 (56) | 132 (44) |
| Somewhat easy | 87 (29) | 122 (43) | 85 (28) | 104 (34) |
| Somewhat difficult | 21 (7) | 46 (16) | 39 (13) | 53 (18) |
| Extremely difficult | 4 (1) | 4 (1) | 9 (3) | 11 (4) |
| Missing data | --- | --- | --- | 1 (<1) |
| **Comfort of the nasal spray nose tip** | | | | |
| Extremely comfortable | 124 (41) | 79 (28) | 136 (45) | 115 (38) |
| Comfortable | 160 (54) | 184 (65) | 157 (52) | 171 (57) |
| Uncomfortable | 9 (3) | 18 (6) | 6 (2) | 12 (4) |
| Extremely uncomfortable | 3 (1) | 2 (<1) | 2 (<1) | 2 (<1) |
| Missing data | --- | --- | --- | 1 (<1) |
| **Gentleness of the nasal spray mist** | | | | |
| Extremely gentle | 160 (54) | 98 (34) | 176 (58) | 150 (50) |
| Moderately gentle | 118 (39) | 126 (44) | 99 (33) | 122 (40) |
| Slightly gentle | 16 (5) | 48 (17) | 26 (9) | 23 (8) |
| Not at all gentle | 2 (<1) | 11 (4) | 0 | 5 (2) |
| Missing data | --- | --- | --- | 1 (<1) |
| **Amount of nasal spray leaking out of nose or down throat** | | | | |
| None of the medication | 87 (29) | 127 (45) | 102 (34) | 116 (38) |
| Some of the medication | 192 (64) | 142 (50) | 182 (60) | 164 (54) |
| A lot of the medication | 13 (4) | 14 (5) | 14 (5) | 16 (5) |
| All of the medication | 4 (1) | 0 | 3 (<1) | 4 (1) |
| Missing data | --- | --- | --- | 1 (<1) |
| **Strength of aftertaste of the nasal spray** | | | | |
| No aftertaste | 156 (52) | 156 (55) | 165 (55) | 164 (54) |
| Weak aftertaste | 107 (36) | 99 (35) | 107 (35) | 114 (38) |
| Moderately strong aftertaste | 30 (10) | 27 (9) | 26 (9) | 22 (7) |
| Extremely strong aftertaste | 3 (1) | 1 (<1) | 3 (<1) | 0 |
| Missing data | --- | --- | --- | 1 (<1) |

**PATIENT PREFERENCE FOR *VERAMYST* VS. FLUTICASONE PROPIONATE NASAL SPRAY (FPNS)**

*Veramyst* was compared with generic FPNS to identify patient preferences for selected product sensory attributes in a multicenter, double-blind, single-dose crossover study.[5] Patients ≥18 years of age with symptomatic seasonal and/or perennial allergic rhinitis (N=127) were randomized 1:1 to receive *Veramyst* 110 mcg followed by FPNS 200 mcg or FPNS followed by *Veramyst*. The primary measure was the overall preference for *Veramyst* or FPNS based on selected sensory attributes. Secondary measures were preferences for and subject ratings of individual sensory attributes. These attributes were assessed immediately after and 2 minutes after each single-dose treatment. At the end of crossover dosing and after completion of all attributes questionnaires, preference for individual attributes of *Veramyst* or FPNS as well as overall preference were evaluated in a third questionnaire. The 3 subject questionnaires were similar to those used previously to evaluate subjects' overall preference for therapy of allergic rhinitis.[6] Since the objective of this study involved subject-rated evaluation during and following crossover dosing, no efficacy data were collected. Therefore, the study outcomes are limited to health outcome endpoints.

A summary and analysis of attribute preference from 120 participants is presented in Figure 1. Overall, significantly more patients preferred *Veramyst* over FPNS (60% vs. 33%). Although 30% or more patients indicated no preference with regard to most sensory attributes, significantly more patients preferred *Veramyst* for scent/odor, immediate taste and aftertaste, less dripping down the throat, and less nose run-off.

**Figure 1. Overall & Selected Product Attribute Preferences for *Veramyst* Compared with Generic Fluticasone Propionate Nasal Spray (FPNS)**




**Enclosure: Prescribing Information for *Veramyst***

**Some information contained in this response may not be included in the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling.**

**In order for GlaxoSmithKline to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 888-825-5249. Please consult the attached Prescribing Information.**

**This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.**

## REFERENCE(S)


1. Data on File. Study FFR104861 (RM2005/00635/00). 2006. *
2. Data on File. Study FFR103184 (HM2005/00492/00). 2006. *
3. Data on File. Study FFR30003 (RM2005/00195/00). 2005. *
4. Data on File. Study FFR30002 (RM2005/00185/00). 2005. *
5. Meltzer E, Stahlman J, Leflein J, et al. A patient preference evaluation study comparing the sensory attributes of fluticasone furoate nasal spray with fluticasone propionate nasal spray [abstract]. In: Abstracts of the Annual Meeting of the American College of Allergy, Asthma & Immunology; November 8-14, 2007; Dallas TX. Abstract P247. (FFU108556) *
6. Meltzer EO, Bardelas J, Goldsobel A, et al. A preference evaluation study comparing the sensory attributes of mometasone furoate and fluticasone propionate nasal sprays by patients with allergic rhinitis. Treat Respir Med 2005;4(4):289-296.*